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Chatzimichalis, M ; Sim, J H ; Huber, A M

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Assessment of a Direct Acoustic Cochlear Stimulator

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Key Words
Direct Acoustic Cochlear Stimulation Partial Implant · Maximum equivalent sound pressure level · Otosclerosis · Round window · Scanning laser Doppler interferometry · Stapes prosthesis · Stapes surgery

Abstract
This study aimed to assess the functional results of a new, active, acoustic-mechanical hearing implant, the Direct Acoustic Cochlear Stimulation Partial Implant (DACS PI), in a preclinical study. The DACS PI is an electromagnetic device fixed to the mastoid by screws and coupled to a standard stapes prosthesis by an artificial incus (AI). The function of the DACS PI-aided reconstruction was assessed by determining: (1) the maximum equivalent sound pressure level (SPL) of the implant, which was obtained from measurements of the volume displacement at the round window in normal and implanted ears, and (2) the quality at the coupling interface between the AI of the DACS and the stapes prosthesis, which was quantified from measurements of relative motions between the AI and the prosthesis. Both measurements were performed with fresh temporal bones using a scanning laser Doppler interferometry system. The expected maximum equivalent SPL with a typical driving voltage of 0.3 V was about 115–125 dB SPL up to 1.5 kHz in reconstruction with the DACS PI, and decreased with a roll-off slope of about 65 dB/decade, reaching 90 dB SPL at 8 kHz. The large roll-off relative to a normal ear was presumed to be a relatively high inductive impedance of the coil of the DACS PI actuator at higher frequencies. Good coupling quality between the AI and the prosthesis was achieved below the resonance (~1.5 kHz) of the DACS PI for all tested stapes prostheses. Above the resonance, the SMart Piston, which is composed of a shape-memory alloy, had the best coupling quality.
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Introduction

The Direct Acoustic Cochlear Stimulation Partial Implant (DACS PI), which was developed by Phonak Acoustic Implants SA (Lonay, Switzerland), is a new implantable device in which a conventional passive stapes prosthesis is connected to and driven by an electromagnetic actuator. This device, with its actuating part, directly stimulates cochlear fluids, bypassing the outer- and middle ears, and thus is expected to be applicable for patients with moderate-to-severe mixed hearing loss [Bernhard et al., 2006; Häusler et al., 2008]. This study aimed to evaluate the functional results of the DACS PI-aided reconstruction with temporal bones (TBs) from human cadavers, using established methods.

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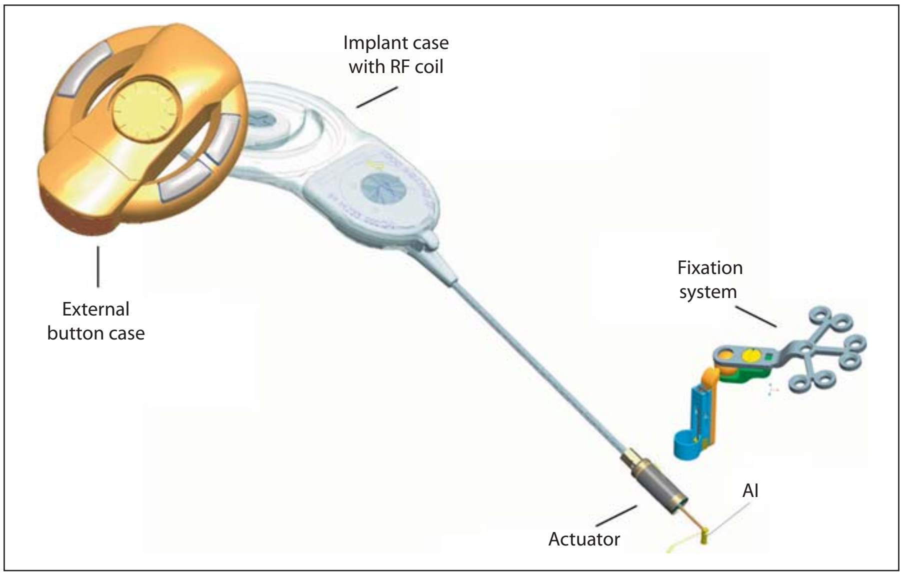

Fig. 1. DACS PI system (provided by Phonak Acoustic Implants SA). The DACS PI system consists of an external button device, an implant with an RF coil and an actuating component, and a fixation system.

Rosowski et al. [2007] developed a test method to obtain the maximum equivalent sound pressure level (ESPL) in reconstruction with implantable middle ear hearing devices (IMEHD). Motions of the stapes in the implanted TB were measured, and the maximum ESPL was obtained in comparison to motions of the stapes in the unimplanted TB. Although reconstructed ears with the IMEHD have motions of the stapes as stimuli to the cochlea at the oval window, by contrast, motions of the stapes prosthesis act as effective stimuli to the cochlea in the reconstructed ears with the DACS PI. The performance of the reconstruction can be evaluated by directly measuring motions of the stapes prosthesis. However, complex spatial motions of a stapes prosthesis are difficult to measure primarily because identification of the orientation of the stapes prosthesis relative to the stapes is not straightforward. Furthermore, possible leakage of cochlear fluids through gaps between the stapes prosthesis and the stapedotomy perforation may result in a less accurate estimation of the functional outcome. As an alternative, our previous study [Sim et al., 2012] introduced a method to assess functional results of reconstruction with stapes prostheses by measuring the volume displacement at the round window (RW). In this study, the maximum ESPL in the reconstruction with DACS PI was obtained in normal and reconstructed ears by comparing the volume displacements at the RW rather than stapes motions. The assumption was that the cochlear structures, including the cochlear fluids and aqueduct, are incompressible, and thus the RW volume displacement represents the amount of stimuli to the cochlea in normal and reconstructed ears, and hence hearing. The compliance of the cochlear structures is presumed to be too large to affect normal air conduction [Gopen et al., 1997; Rosowski et al., 2004; Stenfelt et al., 2004].

In applying the stapes prosthesis as an alternative to the stapes, the coupling between the long process of the incus and the prosthesis plays a crucial role in functional results of the reconstruction. Our previous work showed that reconstruction with tight fixation of the stapes prosthesis onto the incus achieved the best functional results [Huber et al., 2008]. It was also shown that the on-growth of soft tissue after surgery had only a small effect on transmission properties because there was no compensation for incomplete fixation [Sim et al., 2010]. To assess the compatibility of DACS PI with several types of stapes prostheses, the coupling quality between the AI of the DACS PI and three types of stapes prostheses was measured. To quantify the coupling quality, the coupling index, which represents the relative motion between the AI of the DACS PI and the stapes prosthesis at the crimping, was introduced.

Methods

Direct Acoustic Cochlear Stimulator

The DACS PI system consists of an external button device, an implant with an radiofrequency (RF) coil and an actuating component, and a fixation system (fig. 1). The external button device detects and delivers acoustic signals to the implanted component

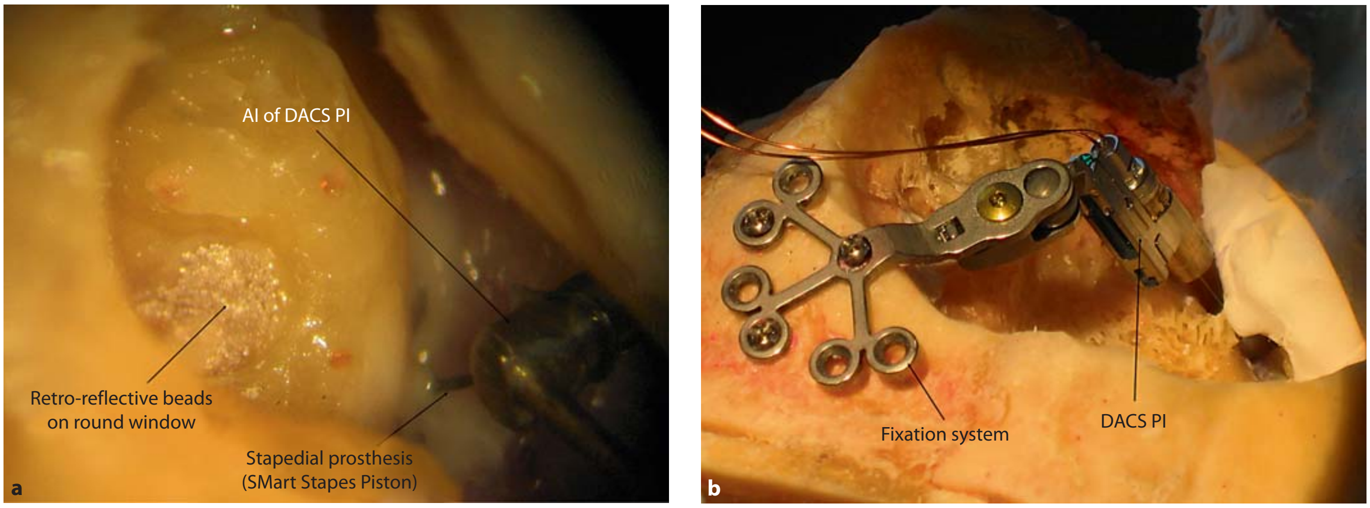

Fig. 2. Reconstruction with DACS PI and the SMart Piston. The SMart Piston fixed to the AI of the DACS PI system (**a**) and fixation of the DACS PI to the TB (**b**). The crura of the stapes were cut by a diode-pumped solid-state laser with a fiber handpiece, the stapes was immobilized using a histoacryl glue, and a hole for the stapes prosthesis was made near the center of the stapes footplate using the laser and a Skeeter drill. The DACS PI system was mounted to the TB with a designated fixation system. The loop of the SMart Piston was fixed to the AI of the DACS PI system using the laser.

via the RF coil. The external button device also provides power for the implanted component. The sound delivered to the implant is transformed into vibration of an artificial incus (AI) constructed at the end of the actuator. A conventional stapes prosthesis is connected to the AI and stimulates the cochlear fluid. The electromagnetic actuator is mounted to the fixation system, which is screwed to the skull. A detailed description of the DACS PI system has been reported by Bernhard et al. [2006] and Häusler et al. [2008].

Maximum ESPL in Reconstruction with the DACS PI

Fresh TBs were harvested within 24 h after death and were placed in a thiomersal solution at 4°C. The TBs were inspected using an operating microscope for possible abnormalities. All experiments were performed within 1 week of the explantation. During the first stage of the measurement, physiological stapes motions in response to acoustic stimuli were examined in TBs, and only TBs whose stapes motions were within the American Society for Testing and Materials (ASTM) standard (F2504–05) [2005] were selected for further measurements. As a result, 10 (6 from men and 4 from women) out of 13 TBs were used for the maximum ESPL in DACS PI-aided ears. The average age for the 10 TBs was 59.9 years.

The volume displacement at the RW was first measured in the unimplanted TB, and was measured again after reconstruction with the DACS PI and stapes prosthesis. In the unimplanted TB, the middle ear cavity was opened from the inferior portion through the jugular bulb and the facial recess, and the lip of the RW niche was carefully removed such that the entire RW membrane was visible at an almost perpendicular angle. The ossicles, ligaments, and muscles of the middle ear were not injured during the procedure, and the tympanic membrane was also left intact. Pure tones of 11 different frequencies from 0.125 to 10 kHz were delivered to an artificial external ear canal (AEEC, about 0.5 ml) individually via a loudspeaker (ER-2, Etymotic Research, USA) that was mounted to the AEEC. The sound pressure in the AEEC was monitored by the probe microphone (ER-7C, Etymotic Research, USA), which was also placed in the AEEC at a distance of approximately 3–5 mm from the center of the tympanic membrane. The maximum allowable voltage (2 V peak) was applied to the loudspeaker to obtain a good signal-to-noise ratio, and the sound pressure level (SPL) in the AEEC as monitored by the microphone was in the range of 90–107 dB SPL for the range of stimuli from 0.125 to 10 kHz. Motions on the RW membrane were measured by a scanning laser Doppler interferometry (SLDI) system (OFV-3001; Polytec GmbH, Germany). After the measurement for the unimplanted TB was completed, reconstruction with the DACS PI was performed. The crura of the stapes were cut by a diode-pumped solid-state laser (Ceralas G5; Biolitec AG, Germany) with a fiber handpiece, the stapes was immobilized using a histoacryl glue (Asculap AG, Germany), and a hole for the stapes prosthesis was made near the center of the stapes footplate using the laser and a Skeeter drill (Medtronic Xomed, Jacksonville, Fla., USA). First, a hole with a smaller diameter was made by the laser, then the accurate diameter of the hole was obtained by the Skeeter drill. The diameter of the stapedotomy hole was made 20% larger than the diameter of the stapes prosthesis (i.e. a hole diameter of 0.6 mm for the prosthesis of 0.5-mm diameter and a hole diameter of 1.0 mm for the prosthesis of 0.8-mm diameter). The DACS PI system was mounted to the TB with a designated fixation system (S50899; Phonak Acoustic Implants SA). A shape-memory alloy prosthesis (SMart Piston, Nitinol-Fluoroplastic; Gyrus ENT LLC, USA) was introduced into the stapedotomy hole, and the prosthesis loop was fixed to the AI of the DACS PI system using the laser. Figure 2 displays the TB reconstructed with DACS PI and the SMart Piston. A total of five DACS PI systems were used, and consistency of the DACS PI systems was verified by measuring the AI using the SLDI system before the system was mounted to the TB. Two different sizes (0.5 mm diameter/4.75 mm length (Ref. 7014–5934) and 0.8 mm diameter/4.75 mm length (Ref. 7014–5924)) of the SMart Pistons were used, and each of the two sizes was applied to two different sets of five TBs (i.e. a total of 10 TBs). Harmonic signals with 0.2-V root mean square (RMS) were applied to the DACS PI for measurement. In both the normal and reconstructed TBs, measurements at approximately 200 targets on the RW membrane were integrated to calculate volume displacements. The motion at each target was assumed to be perpendicular to the RW plane.

Several techniques were used to improve accuracy of the measurements. Micro-reflective beads were coated on the RW membrane to improve reflectivity of the laser beam. The angle between the laser beam of the SLDI system and the RW membrane was obtained using micro-CT technology, and measured motions at the targets on the RW membrane were corrected by the obtained angle. Details of these methods have been described in our previous work [Sim et al., 2012]. All TBs were periodically moistened with a physiological saline solution to prevent drying during preparation and reconstruction of the TBs. The measurement time for both stages (i.e. normal and reconstructed) did not exceed 30 min.

The maximum ESPL was calculated by comparing volume displacements between the normal and reconstructed TBs. In the work by Rosowski et al. [2007], the maximum ESPL $L^{IMEHD}{}_{E_{MAX}}$ in the IMEHD-aided ears was defined as

$$L^{IMEHD}_{E_{MAX}} = 20\log_{10}\left(\frac{v_S^{IMEHD}}{E}\,\frac{p_{EC}^{N}}{v_S^{N}}\,\frac{E_{MAX}}{2\times10^{-5}\,Pa}\right), \qquad (1)$$

where v_S^N and p_{EC}^N were the measured stapes velocity and ear canal pressure in the normal (i.e. not implanted) TB, v_S^{IMEHD} and E were measured stapes velocities and applied voltage in the reconstructed TB with IMEHD, and E_{MAX} was the maximum allowable voltage for the IMEHD. As the volume displacement at the RW was used instead of the stapes motion in this study, the maximum ESPL in equation (1) was modified as

$$L^{DACS}_{E_{MAX}} = 20\log_{10}\left(\frac{VD_{RW}^{DACS}}{E}\,\frac{p_{EC}^{N}}{VD_{RW}^{N}}\,\frac{E_{MAX}}{2\times10^{-5}\,Pa}\right), \qquad (2)$$

where $L^{DACS}_{E_{MAX}}$ was the maximum ESPL in the DACS PI-aided ears, and VD_{RW}^N and VD_{RW}^{DACS} indicated measured volume displacements in normal and reconstructed (with DACS PI) TBs.

SMart Pistons were used exclusively in the experiment for the maximum ESPL, while different types of stapes prostheses were used in experiments for fixation quality.

Fixation Quality at the AI-Prosthesis Interface

The coupling quality between the AI of the DACS PI and the SMart Piston of 0.8 mm diameter was examined in the five TB setups during measurement of the maximum ESPL. To compare the coupling quality of the AI of the DACS PI with different types of stapes prostheses, additional reconstructions with three different types of stapes prostheses of 0.4 mm diameter were performed with an additional three TBs. The K-Piston (titanium, 0.4 mm diameter, 5.0 mm length, Ref. 1006–109; Heinz Kurz GmbH Medizintechnik, Dusslingen, Germany), F-Piston (platinum-fluoroplastic, 0.4 mm diameter, 6.0 mm length, Ref. 11–56234; Medtronic XOMED, USA), and SMart Piston (nitinol-fluoroplastic, 0.4 mm diameter, 4.75 mm length, Ref. 7014–2168; Gyrus ENT LLC) were compared. While K-pistons and F-pistons were manually crimped, the SMart Pistons were fixed by heating with a laser [Rajan et al., 2005; Babighian et al., 2007]. The coupling quality with the SMart Piston and K-piston was examined in two TB reconstructions, and the coupling quality with the F-piston was examined in four TB reconstructions. More reconstructions were used for the F-piston because the first two measurements were inconsistent. The average diameter of the AI of the DACS PI was 0.93 ± 0.027 mm from six (five for SMart Piston of 0.8 mm diameter and one for three different types of stapes prostheses with 0.4 mm diameter) DACS PI systems.

Motions on targets and on the AI and the stapes prosthesis were measured using the SDLI system, and coordinates of the measured targets were recorded by PSV V8.6 software (Polytec GmbH). Figure 3a displays the measured targets on the AI and the stapes prosthesis with the SLDI measurement frame, where the laser beam was along the Z direction and the XY plane (the measurement plane) was normal to the laser beam. The Z direction was approximately parallel to the longitudinal direction of the prosthesis. To quantify the coupling quality, a coupling index, which was calculated from the measurement, was devised. When the coupling between the AI of the DACS and stapes prosthesis was perfectly firm, then it behaved like a rigid body around its coupling interface. As no relative motion between the AI and the stapes prosthesis at its interface was regarded as a condition of the ideal coupling, the expected ideal motion at a target on the prosthesis could be calculated from measured motions at the targets on the AI of the DACS PI, by kinetics of a rigid body. Assuming the prosthesis and the AI move as a rigid body, a measured displacement d_m at a target m on the AI could be related to a displacement d_j at a target j on the stapes prosthesis as

$$d_m = d_j + (Y_m - Y_j)\,\theta_X - (X_m - X_j)\,\theta_Y, \text{ with } m = 1, 2, ..., n \qquad (3)$$

where X_m and Y_m were coordinates of the target m, X_j and Y_j were coordinates of the target j, θ_X and θ_Y were rotational displacements of the rigid body along the X and Y axis, and n was the number of measurement targets on the AI (around 60 targets). Equation (3) could be expressed by a vector notation as following:

$$\mathbf{d}_m = \mathbf{A}_j \mathbf{d}_j^r, \qquad (4)$$

with

$$\mathbf{A}_j = \begin{bmatrix} 1 & (Y_1 - Y_j) & -(X_1 - X_j) \\ \vdots & \vdots & \vdots \\ 1 & (Y_n - Y_j) & -(X_n - X_j) \end{bmatrix}, \qquad \mathbf{d}_m = \begin{Bmatrix} d_1 \\ \vdots \\ d_n \end{Bmatrix},$$

and

$$\mathbf{d}_j^r = \begin{Bmatrix} d_j \\ \theta_X \\ \theta_Y \end{Bmatrix}.$$

Then, with the number n of measured targets on the AI, the vector d_j^r could be calculated by the least-squares error:

$$\mathbf{d}_j^r = (\mathbf{A}_j{}^{T}\,\mathbf{A}_j)^{-1}\,(\mathbf{A}_j{}^{T}\,\mathbf{d}_m). \qquad (5)$$

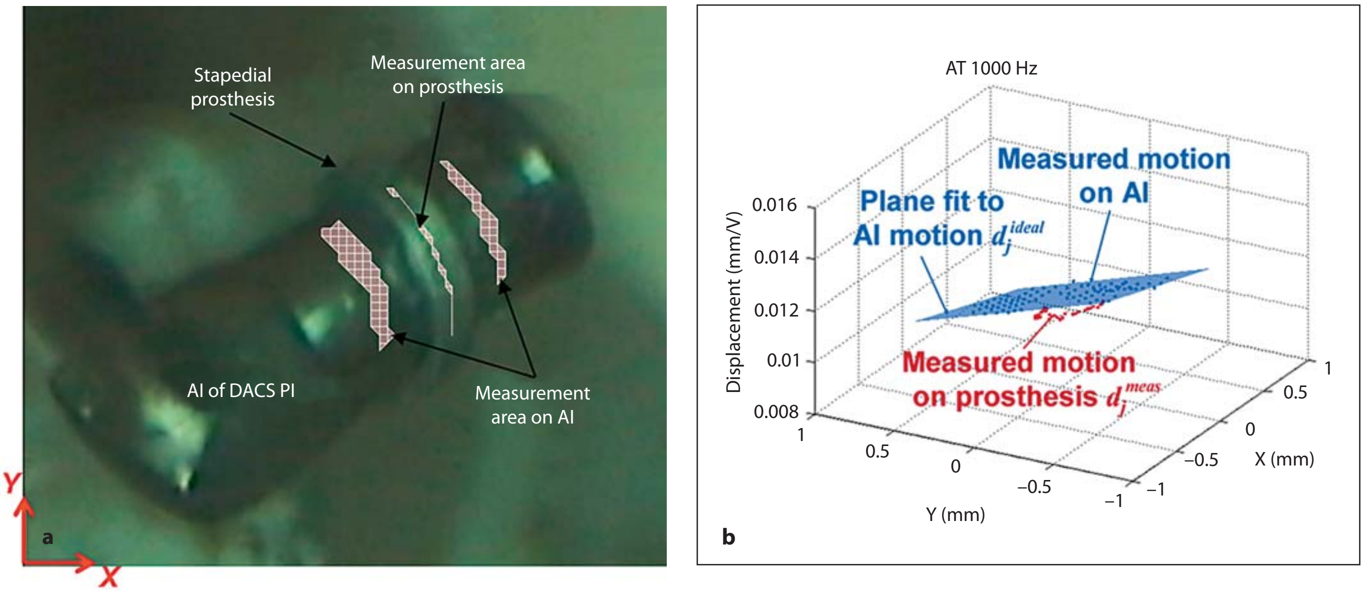

Fig. 3. Measurement of the coupling quality. Measurement targets on the AI and the prostheses with the SLDI measurement (**a**), and representation of the relative motions between the AI motions (blue dots) and the prosthesis motion (red dots) (**b**). In the SLDI measurement frame, the laser beam was along the Z direction, and the XY plane (the measurement plane) was normal to the laser beam. The Z direction was approximately parallel to the longitudinal direction of the prosthesis. The ideal motion d_j^{ideal} at targets on the prosthesis was calculated from the measured motion of the AI assuming a rigid body motion of the AI and prosthesis, and was compared with the measured motion d_j^{meas} of the prosthesis.

The calculated d_j represented the expected displacement at a target j on the stapes prosthesis, which was calculated from measured motions at targets on the AI. Considering the d_j calculated from equation (5) as an ideally expected displacement d_j^{ideal} with a perfect coupling between the AI and the prosthesis, the coupling index CIX_j at the target j was defined by

$$CIX_j = \frac{\left|d_j^{ideal} - d_j^{meas}\right|}{\left|d_j^{ideal}\right|}, \qquad (6)$$

with an actual measured displacement d_j^{meas} at the target j. $|d_j^{ideal} - d_j^{meas}|$, the difference between the ideal and measured displacements at the target j on the piston prosthesis, represented the relative displacement between the AI and the stapes prosthesis at their interface. This corresponded to the distance between 'Plane fit to AI motion' and 'Measured motion at targets on the prosthesis' in figure 3b. Once coupling indices were calculated for each of the targets on the stapes prosthesis (around 20 targets), they were averaged.

$$CIX_{ave} = \frac{\sum_{1}^{m} CIX_j}{m}, \qquad (7)$$

where m was the number of targets j on the stapes prosthesis. This average coupling index could also be represented on a dB scale by

$$CIX\_dB_{ave} = 20\log_{10}(1 + CIX_{ave}) \qquad (8)$$

A larger value in the average coupling index represented poorer coupling (i.e. more transmission loss), while a smaller value represented good coupling.

In calculating the coupling index, both the magnitude and phase of the motion were considered (i.e. the data were treated as complex numbers). Because the measurements were limited within a two-dimensional space (i.e. on the XY plane of the SLDI measurement plane), the coupling index varied with the measurement frame. For consistency, the measurement frame of the SLDI system was aligned such that the laser beam direction (Z direction) of the SLDI system was parallel to the longitudinal direction of the stapes prosthesis.

Results

ESPL in Reconstruction with DACS PI

Figure 4 displays the ASTM standard for 'normal' stapes motion and our measurement of stapes motion for the 10 TBs used for measurements of the RW motion. The stapes motion was measured near the center of the stapes footplate, and the measured motion was corrected by the angle between the laser beam and the footplate plane, to obtain the piston-like component of the stapes motion.

Figure 5 illustrates motions of the AI of the DACS PI measured before the DACS PI was mounted to the TB, with respect to frequency (fig. 5a) and with respect to applied voltage at 0.5 kHz (fig. 5b). In figure 5a, motion of the AI of the DACS PI had an almost flat displacement up

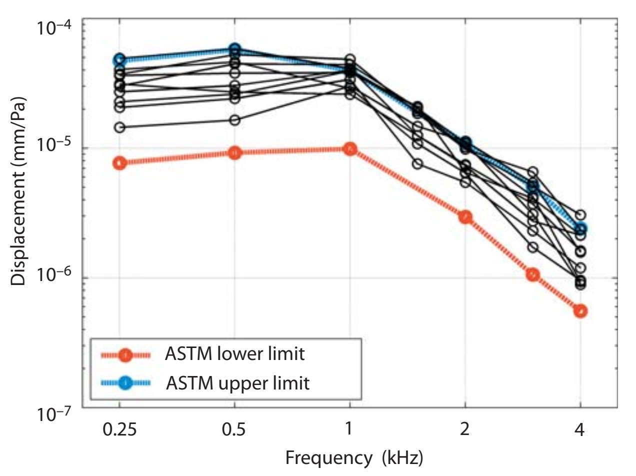

Fig. 4. Displacement at the center of the stapes footplate in normal ears, with ASTM standard. Physiological stapes motions in response to acoustic stimuli were examined in 13 TBs. Ten out of these 13 TBs, which were within the ASTM standard, were selected for further measurements.

to 1.5 kHz where the motion of the AI had its first resonance, and rolled off above 2 kHz with a slope of about 65 dB/decade. The AIs of the six DACS PI systems used in this study showed motions with almost the same magnitude and shape in the frequency domain. In figure 5b, motions at 0.5 kHz were fairly linear up to 0.3 V RMS of the applied voltage. The deviation of the measured value from the linear fitting to measured data at 0.3 V was about 8%.

Figure 6 displays the geometric means (plus standard deviations) of the measured volume displacements at the RW in unimplanted TBs (relative to 94 dB SPL) and in DACS PI-aided TBs (0.2 V in RMS applied to the DACS PI). The magnitude of the RW volume displacement in the DACS PI-aided TBs showed small changes up to its first resonance (approximately 1.5 kHz). With the 0.2-V RMS input, the DACS PI-aided TBs had larger volume displacements of the RW at frequencies below its first resonance relative to the unimplanted TBs with 94-dB SPL input. While the volume displacement at the RW in the DACS PI-aided TBs rolled off with approximately the same slope of 65 dB/decade, the corresponding roll-off slope in the unimplanted TBs was approximately 45 dB/decade up to 4 kHz and approximately 25 dB/decade above 4 kHz. The overall roll-off slope from 1 to 8 kHz in the unimplanted TBs was approximately 40 dB/decade. The difference between the two different sizes of the stapes prostheses (0.5 and 0.8 mm diameter) was not significant ($p > 0.05$) throughout the frequency range of measurement.

Figure 7 displays the maximum ESPL of the DACS PI-aided TBs with SMart Pistons of 0.5 and 0.8 mm diameters, which were calculated from results shown in figure 6. Although more than 0.5 V would have been permissible to the DACS PI, 0.3 V RMS was used as the maximum voltage in the calculations (E_{MAX} in equation (2)) because the linearity of the AI was guaranteed up to this level. It was assumed that the results with the 0.3-V RMS input would be linearly proportional to the results with the 0.2-V RMS input, and actual measurements were not taken with this input. The maximum ESPL was more than 110 dB SPL up to 1.5 kHz, and decreased with frequency at higher frequencies, for both sizes of the stapes prostheses. At 8 kHz, the maximum ESPL was approximately 90 dB. A difference between the two sizes of the stapes prostheses was observed at 4 and 6 kHz, but the difference was in the order of 5–10 dB, which was not significant.

Quality of the Coupling between the AI and Piston Prostheses

Figure 8 displays the mean values of the average coupling indices with the corresponding standard deviations for the SMart Piston of 0.8 mm diameter ($n = 5$). The results showed a trend for coupling quality to be worse at high versus low frequencies. The value of the coupling indices in decibels was less than 1 dB (12%) up to 1 kHz, and was maximal at 6 kHz with a value of 2.1 ± 1.6 dB (27%).

Figure 9 displays the coupling indices for the three different types of stapes prostheses of 0.4 mm diameter. While the coupling indices were below 0.6 dB (7%) up to 1 kHz for all three types indicating good coupling qualities, the coupling indices at the higher frequencies differed with the type of piston prosthesis. The coupling index for the SMart Pistons was less than 1 dB (12%) from 0.25 to 6 kHz for both measurements (SMart Pistons No. 1 and 2). There were differences in the coupling quality with the F-Pistons. F-Pistons No. 1 and 4 had coupling indices of less than 3.7 dB (53%) up to 4 kHz but large coupling indices (more than 6.0 dB (100%)) at 6 kHz. F-Piston No. 2 had a maximum coupling index of 3.5 dB at 2 kHz, but the coupling indices were lower than 1.7 dB at other frequencies. F-Piston Np. 3 had coupling indices lower than 2 dB from 0.25 to 6 kHz, similar to the SMart Pistons. The two K-Pistons showed a trend for lower cou-

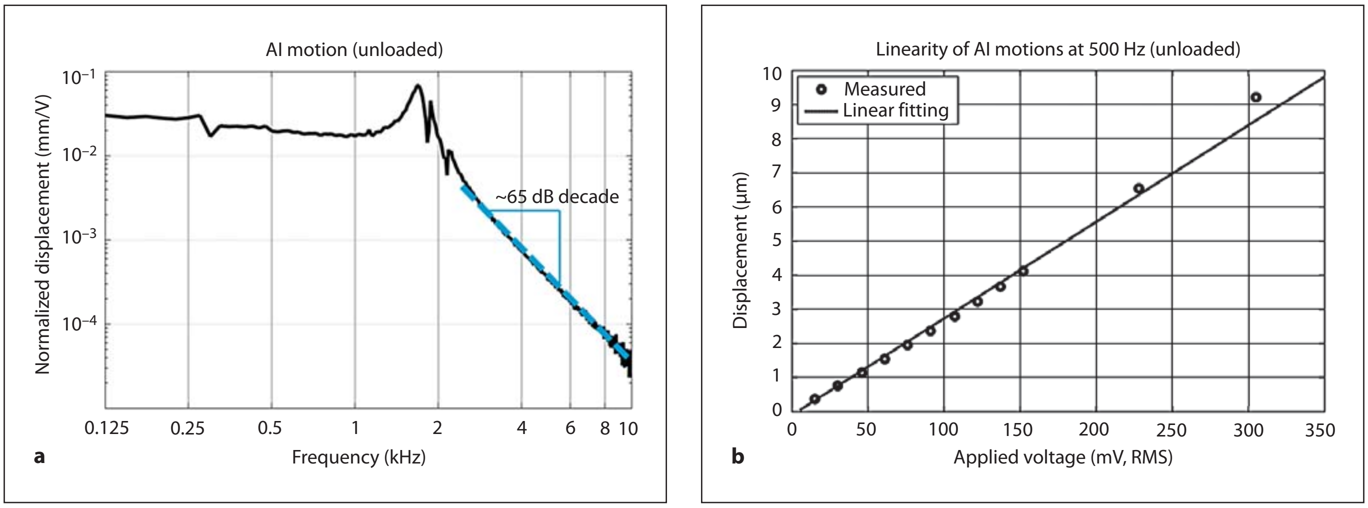

Fig. 5. Motions of the AI of the DACS PI measured before mounted to the TB with respect to frequency (**a**) and applied voltage at 0.5 kHz (**b**). Motion of the AI of the DACS PI had an almost flat displacement up to 1.5 kHz where the motion of the AI had its first resonance, and rolled off above 2 kHz with a slope of about 65 dB/decade. Motions at 0.5 kHz were fairly linear up to 0.3 V RMS of the applied voltage.

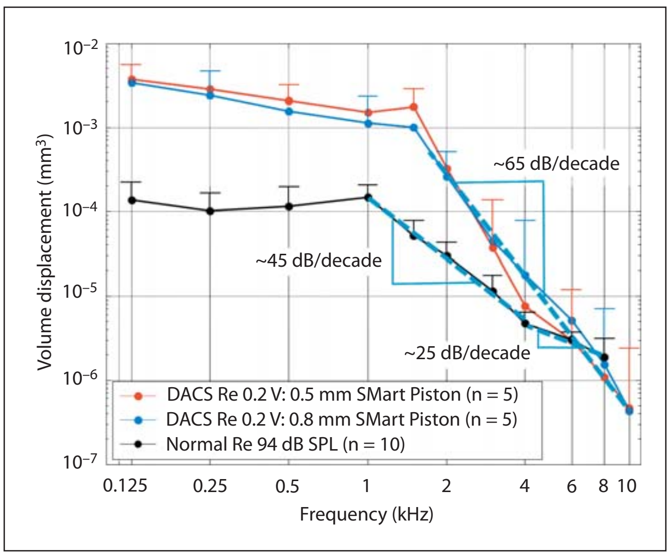

Fig. 6. Volume displacement at the RW in unimplanted TBs (94 dB SPL input) and in DACS PI-aided TBs (0.2 V RMS input) with SMart Piston shape-memory alloy prostheses. Vertical lines indicate standard deviations. The DACS PI-aided TBs had relatively large volume displacements of the RW at frequencies below its first resonance. While the volume displacement at the RW in the DACS PI-aided TBs rolled off with approximately the same slope of 65 dB/decade, the corresponding roll-off slope in the unimplanted TBs was approximately 45 dB/decade up to 4 kHz and approximately 25 dB/decade above 4 kHz. The difference between the two different sizes of the stapes prostheses (0.5 and 0.8 mm diameter) was not significant ($p > 0.05$) throughout the frequency range of measurement.

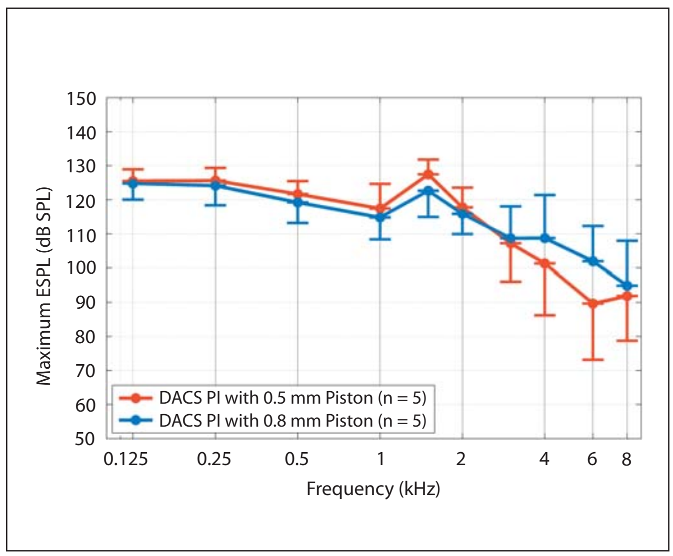

Fig. 7. The maximum ESPL in DACS PI-aided TBs with SMart Piston shape-memory alloy prostheses. Vertical lines indicate standard deviations. The maximum ESPL with 0.3 V RMS was more than 110 dB SPL up to 1.5 kHz, and decreased with frequency at higher frequencies, for both sizes of the stapes prostheses.

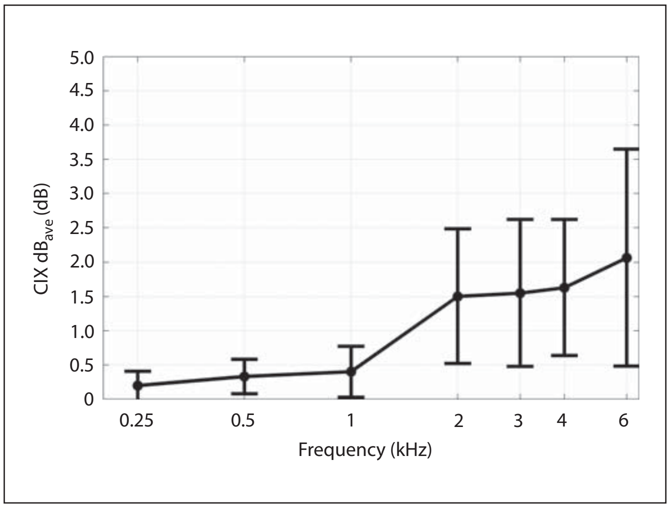

Fig. 8. Mean values of the coupling index (CIX) in decibels for the SMart Piston of 0.8 mm diameter. Vertical bars indicate the corresponding standard deviations. The coupling quality was worse in the high (2.1 ± 1.6 dB at 6 kHz) versus the low frequencies (<1 dB up to 1 kHz).

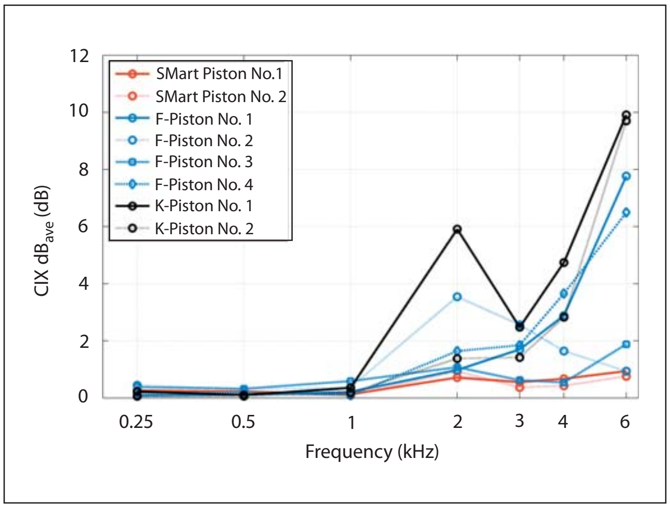

Fig. 9. Coupling index (CIX) in decibels for the three different types of the stapes prostheses. While the coupling indices were below 0.6 dB up to 1 kHz for all three types, the coupling indices at the higher frequencies differed with the type of piston prosthesis. The SMart Piston showed the best coupling quality at the higher frequencies (<1 dB up to 6 kHz).

pling indices up to 1 kHz (less than 1.5 dB (19%)) and very high coupling indices in the higher frequencies (more than 9.5 dB (200%) at 6 kHz). At 2 kHz, the two K-Pistons had large individual differences in coupling indices (5 dB).

Discussion

In this study, functional outcomes of reconstruction with a DACS PI were evaluated from measurements of volume displacements at the RW in TBs. With a constant voltage on the DACSP PI from 0.25 to 6 kHz, implanted TBs showed excellent sound transmission up to 1.5 kHz (maximum ESPL >110 dB SPL), where the actuator of the DACS PI has its first resonance. Above this resonance, the functional outcome was sloping, reaching a maximum ESPL of 90 dB SPL at 8 kHz. This was caused by different roll-offs of the volume displacement at the RW between the normal and reconstructed TBs. While the roll-off slope of about 65 dB/decade was found in reconstruction with the DACS PI, the corresponding slope was in the range of 25–45 dB/decade with an overall slope of 40 dB/decade in normal TBs.

While a constant voltage through the frequency range of measurement was applied to the DACS PI actuator in our study, input power on the DACS PI actuator was maintained constant in a study by Bernhard et al. [2006]. In their study, the desired resonance frequency and roll-off slope above the resonance frequency were obtained from the middle ear transfer function of a fresh TB, and were denoted as 1 kHz and 40 dB/decade, respectively. These findings are in agreement with the characteristics of normal ears determined in our study (fig. 6). With the constant input power in their measurement, the DACS PI system showed the resonance frequency to be around 1 kHz and the roll-off slope to be about 45 dB/decade after the resonance, results which were similar to their desired values. The difference of the roll-off slope between their work (with constant power supply) and our study (with constant voltage) is presumed to be mainly due to relatively high inductive impedance of the coil inside the DACS PI actuator at higher frequencies.

The DACS PI was designed for patients with severe to profound mixed hearing loss due to advanced otosclerosis. By directly stimulating the cochlea, it is bypassing the sound conduction of the middle ear and is therefore particularly effective with impaired middle ear sound transmission due to a fixed ossicular chain. In such patients, the device's amplification is effectively with respect to measured bone conduction thresholds, which may be 10–50 dB better than air-conduction thresholds.

The device has potential benefit for patients with mixed hearing loss when the conductive component is due, for example, to advanced otosclerosis, trauma, infections, or complex ear atresia combined with inner ear deformities. While the ESPL is expected to be sufficient for severe to profound mixed hearing loss, the device is presumed to be impractical for use in pure sensorineural hearing loss as its placement may interfere with a normal ossicular chain.

The maximum ESPL was compared for the two different sizes of the SMart Piston, and was similar for both sizes. Considering only the ratio of the cross-sectional areas (=2.56) between the two different sizes, the maximum SPLs were expected to differ by approximately 8 dB (i.e. $20\log 2.56 \approx 8$), if motion of the prosthesis for the two different sizes has an equal magnitude and direction. Three possible reasons may account for the non-significant differences between the two sizes. First, the SMart Piston of 0.8 mm diameter (3.388 mg) is twice as heavy as the one of 0.5 mm diameter (1.601 mg). The greater inertia with the larger size results in a smaller magnitude of motion. Second, the larger size has a larger fluid impedance due to the greater contact area with fluid at the prosthesis end. Third, at the interface between the piston prosthesis and the piston hole, the prosthesis with the larger diameter has a greater contact area with the side wall of the hole. The increased contact area is expected to cause an increase in friction. In addition, while the hole for the SMart Piston of 0.5 mm diameter could be made inside the stapes footplate, the hole for the SMart Piston of 0.8 mm diameter was usually made through the peripheral cochlea bone as well as the stapes footplate (the diameter of the hole for the SMart Piston of 0.8 mm diameter was 1.0 mm, and the length of the short axis of the footplate was around 1.0 mm). These may cause more frictional forces between the prosthesis and the side wall of the hole in reconstruction with the SMart Piston of 0.8 mm diameter.

In comparing the functional outcomes with the two different prosthesis sizes, it would be optimal to try both with each TB. However, attaching the two sizes to the same TB without changing any of the TB properties was technically difficult. A time-dependent change of the properties of the TB was also of concern, even though we moistened the TB during preparation between the measurement stages. As the DACS PI-aided ear did not use the existing middle ear structure and the stapes was immobilized, it was assumed that the RW volume displacement reflected only stimulation by the DACS-PI and the prosthesis with incompressibility of the cochlear structures. However, the relative positions and orientations between the AI, the prosthesis, and the stapes footplate could be different for each TB preparation, and this was a limitation in comparing the two different sizes of prostheses in this study.

The AI of the DACS showed good coupling quality with the SMart Piston of both 0.4 and 0.8 mm diameter from 0.25 to 6 kHz. Coupling qualities with the F-Piston and K-Piston were lower or more variable above 2 kHz. Better coupling of the self-crimping prosthesis with the incus has also been observed in stapes surgeries [Huber et al. 2008]. However, in such surgeries, the relative difference between the self-crimping and conventional stapes prostheses was 1–4 dB, and was more uniformly distributed in the frequency range of 0.125–6 kHz. The sources for larger differences in coupling quality between the self-crimping prosthesis and other prostheses in DACS PI-aided ears at high frequencies were not investigated systematically; however, it is likely that the self-crimping prosthesis provided better coupling above 2 kHz in the DACS PI-aided ears. Therefore, intra-operative examination of the coupling quality between the AI of the DACS PI and the stapes prosthesis is unnecessary when self-crimping prostheses are used surgically.

Conclusion

The effectiveness of reconstruction with a DACS PI was assessed using the maximum ESPL obtained from the measurement of the volume displacement at the RW, and by coupling qualities at the interface between the AI of the DACS and the stapes prosthesis. The maximum ESPL (for an applied voltage of 0.3 V) in reconstruction with a DACS PI was excellent (>110 dB up to the resonant frequency of 1.5 kHz, and >90 dB for the higher frequencies). The difference of the maximum ESPL between the low and high frequencies was due to relatively high inductive impedance of the DACS PI actuator for higher frequencies, and is expected to be smaller when constant input power on the DACS PI actuator is the parameter. The coupling quality between the AI and the prosthesis was best when a SMart Piston was used. Therefore, a self-crimping prosthesis is recommended for use with the DACS PI system.

References

American Society for Testing and Materials (ASTM) International F2504-05 Standard Practice for Describing System Output of Implantable Middle Ear Hearing Devices. Philadelphia, ASTM, 2005.

Babighian G, Fontana M, Caltran S, Ciccolella M, Amadori M, De Zen M: The heat-activated stapes prosthesis 'SMart' Piston: technique and preliminary results. Adv Otorhinolaryngol 2007;65:190–196.

Bernhard H, Stieger C, Perriard Y: New implantable hearing device based on a micro-actuator that is directly coupled to the inner ear fluid. Conf Proc IEEE Eng Med Biol Soc 2006;1:3162–3165.

Gopen Q, Rosowski JJ, Merchant SN: Anatomy of the normal human cochlear aqueduct with functional implications. Hear Res 1997;107:9–22.

Häusler R, Stieger C, Bernhard H, Kompis M: A novel implantable hearing system with direct acoustic cochlear stimulation. Audiol Neurotol 2008;13:247–256.

Huber AM, Veraguth D, Schmid S, Roth T, Eiber A: Tight stapes prosthesis fixation leads to better functional results in otosclerosis surgery. Otol Neurotol 2008;29:893–899.

Rajan GP, Atlas MD, Subramaniam K, Eikelboom RH: Eliminating the limitations of manual crimping in stapes surgery? A preliminary trial with the shape memory Nitinol stapes piston. Laryngoscope 2005;115:366–369.

Rosowski JJ, Songer JE, Nakajima HH, Brinsko KM, Merchant SN: Clinical, experimental, and theoretical investigations of the effect of superior semicircular canal dehiscence on hearing mechanisms. Otol Neurotol 2004;25:323–332.

Rosowski JJ, Chien W, Ravicz ME, Merchant SN: Testing a method for quantifying the output of implantable middle ear hearing devices. Audiol Neurotol 2007;12:265–276.

Sim JH, Chatzimichalis M, Huber AM: The influence of postoperative tissue formation on sound transmission after stapes surgery. Hear Res 2010;263:38–42.

Sim JH, Chatzimichalis M, Röösli C, Laske R, Huber AM: Objective assessment of stapes surgery from round window motion measurement. Ear Hear 2012, in print (DOI: 10.1097/AUD.0b013e318258c7a6).

Stenfelt S, Hato N, Goode RL: Fluid volume displacement at the oval and round windows with air and bone conduction stimulation. J Acoust Soc Am 2004;115:797–812.